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MAR 16 2012

510(k) Summary

510(k) SUMMARY

This 510(k) Summary is provided per the requirements of section 807.92(c).

Owner Name:	Bard Electrophysiology Division of C.R. Bard, Inc.
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	Lowell, MA 01851
Phone Number:	978-323-2348
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Date of Summary:	December 22, 2011
Device Trade Name:	LabSystem™ PRO EP Recording System
Device Common Name:	Programmable Diagnostic Computer
Classification Name:	Programmable Diagnostic Computer
Predicate Device(s):	Bard LabSystem PRO EP Recording System (K031000/June 3, 2003)

V3.1 Software for the Bard LabSystem PRO EP Recording System (K101331/October 8, 2010)

GE Medical Systems Information Technologies, MAC-LAB/CARDIOLAB EP/COMBOLAB System (K032577/October 10, 2003)

Device Description:

The V2.6 software for the LabSystem™ PRO EP Recording System is a bidirectional software interface that links the Bard LabSystem PRO EP Recording System with the Biosense-Webster CARTO 3 mapping/navigation system. The V2.6 software also incorporates the core recording system functionality of the released V2.4b software for the LabSystem PRO EP Recording System. The joint integrated solution provides a single repository for the resulting CARTO 3D electro-anatomical map and procedure information collected by LabSystem PRO EP Recording System. This interface will enhance the usability of the two systems when used in tandem. This will result in a workflow improvement, more streamlined data management, and simpler review of case details. The information will be shared via a network link using a BWI communication protocol.

The V2.6 software is intended for use with the LabSystem PRO EP Recording System (K031000). The LabSystem™ PRO EP Recording System is a microprocessor based data acquisition system that is used during electrophysiology procedures to acquire ECG, intracardiac, pressure and digital data from other devices like fluoroscopic systems and RF generators. The ECG, intracardiac and pressure data are acquired by an amplifier that is connected to the patient via ECG leadwires and catheters. It does not transmit alarms nor does it have arrhythmia detection capabilities.

Indications for Use:

The Bard LabSystem EP Laboratory is a computer and software driven data acquisition and analysis tool designed to facilitate the gathering, display, analysis by a physician, pace mapping and storage of cardiac electrophysiologic data.

When integrated with the Biosense Webster® CARTO™ 3 system, the Bard® LabSystem™ PRO EP Recording System is designed to: a) send patient demographics to Biosense Webster® CARTO™ 3, and b) acquire (from Biosense Webster® CARTO™ 3), store and display: i) synchronized 3D mapping events, ii) stimulation pacing data, and iii) images of completed 3D electro-anatomical maps of the human heart. The 3D mapping events and images are created by the Biosense Webster® CARTO™ 3 device and stored on the Bard® LabSystem™ PRO EP Recording System for review and insertion into the final clinical report. Integration also supports bidirectional communication of stimulation pacing channel selection and information sharing between the two systems.

Comparison to Predicate Devices:

The predicate devices for this 510(k) Premarket Notification are the LabSystem™ PRO EP Recording System (K031000), V3.1 Software for the LabSystem PRO EP Recording System (K101331) and the GE CARDIOLAB EP System (K032577). The Indications for Use for the LabSystem PRO EP Recording System V2.6 software and the CardioLab EP System (K032577) are essentially the same.
Both of these devices are electrophysiology recording systems that are used for the same intended purpose. Both systems are intended for use under the direct supervision of a licensed healthcare practitioner to acquire, filter, digitize, amplify, and record electrical signals obtained during electrophysiological studies and related procedures conducted in an electrophysiological laboratory. Both systems acquire signal types which include ECG signals, direct cardiac signals, and pressure recordings. Both systems obtain physiological parameters such as diastolic, systolic and mean blood pressure, heart rate and cycle length which are derived from the signal data, displayed and recorded. Both systems allow the user to monitor the acquisition of data, review the data, store the data, perform elementary caliper-type measurements of the data and generate reports on the data. Both systems acquire, amplify, display and record data received from other medical devices typically used during these procedures, such as imaging devices and RF generators. Both systems do not transmit alarms nor does not have arrhythmias detection capabilities.

Both Systems have the capability to integrate with the Biosense Webster®, CARTO™ 3 system, to send patient demographics to Biosense Webster® CARTO™ 3, and acquire (from Biosense Webster® CARTO™ 3), store and display: i) synchronized 3D mapping events, ii) stimulation pacing data, and iii) images of completed 3D electro-anatomical maps of the human heart. The 3D mapping events and images are created by the Biosense Webster® CARTO™ 3 device and stored on the Bard® LabSystem™ PRO EP Recording System for review and insertion into the final clinical report. Integration also supports bidirectional communication of stimulation pacing channel selection between the two systems.

The hardware, base software and firmware that are currently utilized in the LabSystem PRO EP Recording System (K031000 and K101331) are identical to the base software and firmware for the V2.6 software for the LabSystem PRO EP Recording System.

Summary of Non-Clinical Testing:

The LabSystem™ PRO EP Recording System is developed and produced in accordance with 21 CFR 820.30 Quality System Regulations. The software product is developed and tested in accordance with the following industry standards. Use of the IEEE standards is voluntary.

IEEE Standard 730-1995	Software Quality Assurance Plans
IEEE Standard 829-1983 (*1991)	Software Test Documentation
IEEE Standard 1012-1986 (*1992)	Software Verification and Validation Plans
IEEE Standard 830-1993	Software Requirement Specifications
IEEE Standard 1008-1987 (*1993)	Software Unit Testing

*Reaffirmed by IEEE in year stated.

EN 60601-1-2:2007 EMC, Radiated emissions and Conducted emissions requirements

EN 60601-1:2005 Patient Leakage current (Section 19, Table IV, Type CF, 50uA)

Software qualification is performed in-house on the System with results that meet acceptance criteria, thus confirming the safety and effectiveness of each functional aspect of the LabSystem™ PRO EP Recording System.

Substantial Equivalence:

The LabSystem™ PRO EP Recording System, subject of this 510(k), is substantially equivalent to the predicate devices. They have the same Indications for Use, principles of operation, and the technological characteristics support a determination of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Bard Electrophysiology Division of C.R. Bard, Inc.
c/o Ms. Anastasia C. Randall
Regulatory Affair Manager
55 Technology Dr.
Lowell, Massachusetts 01851

APR 3 2012

Re: K113811
Trade/Device Name: LabSystem PRO EP Recording System V2.6
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II (two)
Product Code: DQK
Dated: February 24, 2012
Received: February 27, 2012

Dear Ms. Randall:

This letter corrects our letter of March 16, 2012 regarding the incorrect software version identified on the clearance letter.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use Statement

Indications for Use

510(k) Number (if known): K113811

Device Name: LabSystem™ PRO EP Recording System

Indications for Use:

V2.6 software for the LabSystem™ PRO EP Recording System Indication: The Bard LabSystem™ EP Laboratory is a computer and software driven data acquisition and analysis tool designed to facilitate the gathering, display, analysis by a physician, pace mapping and storage of cardiac electrophysiologic data.

When integrated with the Biosense Webster® CARTO™ 3 system, the Bard® LabSystem™ PRO EP Recording System is designed to: a) send patient demographics to Biosense Webster® CARTO™ 3, and b) acquire (from Biosense Webster® CARTO™ 3), store and display: i) synchronized 3D mapping events, ii) stimulation pacing data, and iii) images of completed 3D electro-anatomical maps of the human heart. The 3D mapping events and images are created by the Biosense Webster® CARTO™ 3 device and stored on the Bard® LabSystem™ PRO EP Recording System for review and insertion into the final clinical report. Integration also supports bidirectional communication of stimulation pacing channel selection and information sharing between the two systems.

Contraindications: None

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K113811